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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/483,434	01/14/00	MILLER J	14014.0360

HM22/0519

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EXAMINER	
LEFFERS JR,G	
ART UNIT	**PAPER NUMBER**
1636	5

DATE MAILED: 05/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/483,434	Miller, et al.
Examiner	**Group Art Unit**
Gerald G. Leffers Jr.	1636

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-14* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-14* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 7, drawn to a method of delivery of a biologically active molecule, classified in class 514, subclasses 1, 2 44; class 435, subclass 440.

II. Claims 4-5, drawn to drawn to a method of delivering a biologically active molecules to cells of a tissue or organ in a human body, classified in class 514, subclasses 1, 2 44; class 435, subclass 440.

III. Claim 6, drawn to a method of delivering an oligonucleotide to a cell with PEI, classified in class 514, subclasses 1, 2 44; class 435, subclass 440.

IV. Claim 8, drawn to a method of delivering a marker to a cell, classified in class 514, subclass 1.

V. Claims 9-10, drawn to a composition comprising a nucleic acid-PEI-avidin complex, classified in class 536, subclass 23.1; class 514, subclass 44.

VI. Claims 11-14, drawn to cells comprising a covalently linked surface receptor molecule, classified in class 435, subclasses 243, 325 and 410.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-IV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I-IV comprise steps that are not necessarily required or present in the methods of the other groups: contacting a cell in vitro with a biologically active molecule-ligand complex (Group I), contacting a cell within tissue or an organ of an organism with a biologically active molecule-ligand complex (Group II), contacting a cell with an oligonucleotide-PEI complex (Group III) and contacting a cell with a marker molecule-ligand complex (Group IV). The end results of the methods are different: delivery of a biologically active molecule to a cell not necessarily within an organism (Group I), delivery of a biologically active molecule to a cell within the tissue or an organ of an organism (Group II), delivery of an oligonucleotide-PEI complex to a cell (Group III) and delivery of a marker molecule to a cell (Group IV). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group V and Groups I-II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions of Group V can be used as a source of the nucleic acid for PCR amplification and subsequent subcloning purposes.

Inventions of Group V and Groups III-IV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The compositions of Group V are not used in the methods of Groups III-IV. The operation, function and effects of the compositions of Group V (i.e. delivery of a nucleic acid to the surface of a cell bearing a covalently-linked cell surface receptor) are completely different and distinct from the operation, function and effects of the methods of Groups III-IV which deliver a PEI-nucleic acid complex to any cell (Group III) or deliver a marker molecule (e.g. a florescent small molecule) to the surface of a cell bearing a covalently-linked cell surface receptor (Group IV). Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups V and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention of Group VI has separate utility such as a source of the desired nucleic acid for PCR amplification and subsequent cloning into different vectors. See MPEP § 806.05(d).

Inventions of Group VI and Groups I-IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Group VI can be used for

transformation by nucleic acids by other, traditional means (e.g. viral vectors, electroporation, etc.) or as evidenced by the different methods of Groups I-IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of the non-patent literature search for each of Groups I-IV is not required for each of the other groups (e.g. Group I-in vitro transfection protocols, Group II-in vivo or ex vivo transfection protocols, Group III-polycation transfection protocols and Group IV-biological markers), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: Group I Species I (biologically active molecules), please pick one member of the Markush group of claim 2.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 2 are generic for Group I Species I.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Mary Miller on 5/10/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

GLJ

G. Leffers, Jr.

Patent Examiner

Art Unit 1636

Terry A. McKelvey

TERRY MCKELVEY
PRIMARY EXAMINER

May 16, 2000